

REMARKS

Applicants have amended Claims 2, 3, 22, 39, 42, 43, 47 and 49. Applicants are not conceding in this Application that the amended claims are not patentable, as the present claim amendments are only for facilitating expeditious prosecution of the allowable subject matter noted by the Examiner. Applicants respectfully reserve the right to pursue these and other claims in one or more continuation or divisional patent applications.

I. STATUS OF THE CLAIMS

At the time of the Office Action, Claims 1-40 and 42-49 were pending. Claims 2, 3, 8, 9, 22, 39 and 42-49 are currently under examination. Claims 2, 3, and 39-43 are objected to for informalities. Claims 2, 3, 22, 39, 42, and 47-49 are rejected. Applicants respectfully note that Claim 22 was previously allowed in its current form, but has been rejected in the pending Office Action.

II. INTERVIEW

Applicants would like to thank Examiner Marvich for extending the courtesy of the telephonic Interview with attorney Nicholas Landau held December 12, 2007. Discussed were the objections to Claims 2, 3, 8, 9, 39, 42, and 43; the enablement rejections of Claims 2, 3, 22, 39, 42, 47, and 49; and the obviousness rejection of Claim 48.

Agreement was reached with regard to the objections to Claims 2, 3, 8, 9, 39, 42, and 43.

It was agreed that the objections to Claims 2 and 3 could be overcome if the preambles to these claims are amended to recite "capable of local gene expression in plants wherein expression is induced by elicitor treatment, pathogen infection, or both."

It was agreed that the objection to Claim 39 could be overcome if Claim 39 is amended into independent form.

It was agreed that the objection to Claim 42 could be overcome if Claim 42 is amended to replace "the said" with "the."

It was agreed that the objection to Claim 43 could be overcome if Claim 43 is amended to recite "...wherein ~~at least one of the said~~ two or more *cis*-acting elements..."

Agreement was reached with regard to the enablement rejections of Claims 2, 3, 22, 39, 42, 47, and 49. The Examiner acknowledged that Claims 8 and 9 should have been included in the rejection. It was agreed that the rejections could be overcome if the claims are limited to *cis*-acting elements "sufficient to direct pathogen-elicitor-specific expression" or "sufficient to direct; pathogen-elicitor-specific expression of a nucleic acid sequence, pathogen-infection-specific expression of a nucleic acid sequence, or both."

No agreement was reached with regard to the obviousness rejection of Claim 48.

Agreement was reached on allowable form of the claims.

III. OBJECTIONS TO THE CLAIMS

Claims 2, 3, and 39-43 are objected to because of informalities. Applicants have amended claims 2, 3, and 39-43 in accordance with the Examiner's recommendations in the Office Action. Applicants respectfully request reconsideration and withdrawal of the objections.

The Office Action Summary lists Claims 44 and 45 as objected to. However, the Office Action does not explain the basis for the objections. It appears that Claims 44 and 45 are objected to because they depend on Claim 43, which was the subject of an objection. As the objection to Claim 43 has been satisfied, it is believed that the objections to Claims 44 and 45 have been satisfied. Applicants respectfully request that the Examiner withdraw the objections to Claims 44 and 45.

IV. REJECTION OF CLAIMS UNDER 35 U.S.C. §112

Claims 2, 3, 22, 39, 42, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, for the stated reason that the specification does not enable any person skilled in the art to make or use the invention commensurate in scope with the claims. The Office Action states that "the specification, while being enabling for an element sufficient for induction of pathogen elicitor expression, does not reasonably provide enablement for any other embodiment"

During the interview, it was agreed that the Specification is enable for an element sufficient for induction of pathogen-infection-specific expression."

Applicants do not agree that the Specification is non-enabling for other embodiments of the invention. However, Applicants offer the following amendments solely for the purpose of

expediting prosecution of the embodiments which the Examiner deems enable to allowance. Applicants have amended the element of "cis-acting elements sufficient to direct elicitor-specific expression" to "cis-acting elements sufficient to direct pathogen-elicitor-specific expression" or "sufficient to direct: pathogen-elicitor-specific expression of a nucleic acid sequence, pathogen-infection-specific expression of a nucleic acid sequence, or both." Applicants submit that this claim element is fully enabled and supported by the specification, and does not constitute new matter (*see, for example*, page 3 first full paragraph "elicitors prepared from, *e.g.*, pathogens such as fungi or bacteria or derivatives thereof;" page 4 first paragraph referring to fungal elicitors; page 4 paragraph 3 "the term 'pathogen' includes, for example, bacteria, viruses, fungi and protozoa as well as elicitors prepared therefrom;" page 16 last paragraph describing *cis*-acting elements "capable of conferring elicitor inducible or pathogen gene expression;" page 24 paragraph 2 describing elements responsive to fungal elicitors; pages 39-40 Example 8, demonstrating induction in response to infection by *Pseudomonas syringae*, exposure to flagellin 22, and infection by *Peronospora parisitica*; Figures 4-8, showing induction in response to exposure to Pep25).

As Applicants have amended the claims to recite only those embodiments that the Examiner agrees are enabled by the Specification, Applicants respectfully submit that the rejection is now moot. As such, Applicants respectfully request the Examiner withdraw the rejections and allow the claims.

V. REJECTION OF CLAIMS UNDER 35 U.S.C. §103

Claim 48 is rejected as obvious under 35 U.S.C. §103 over the combination of Van de Löcht, Pears, Searle, and Comai (all of record). The Office Action states that Van de Löcht teaches a promoter comprising SEQ ID NO. 11, and that the secondary references teach the utility of multimeric elements in increasing the inducibility of promoters.

Applicants respectfully request that this rejection be withdrawn for at least the following reasons. All of the cited references teach away from a promoter comprising two copies of SEQ ID NO. 11; therefore, it would not have been obvious to modify the promoters of Van de Löcht to create the claimed chimeric promoter. In support of Applicant's argument, Applicants refer the Examiner to the declaration of Dr. Imre Somssich, submitted to the U.S. Patent and Trademark Office on March 12, 2007.

A. VAN DE LÖCHT TEACHES AWAY FROM THE CLAIM

Although van de Löcht's promoters overlapped with a portion of SEQ ID NO: 11, van de Löcht does not disclose or suggest that SEQ ID NO: 11 is a chimeric promoter capable of mediating local gene expression in plants upon pathogenic infection. In fact, van de Löcht clearly misses the importance of SEQ ID NO: 11 to elicitor-mediated expression. Van de Löcht does not recognize the importance of the region from positions -47 to -52, which is part of SEQ ID NO: 11. In addition, Van de Löcht expresses the belief that the region from -76 to -168 is critical to elicitor-mediated expression. As the claims are directed to the region from -76 to -47 (SEQ ID NO: 11), van de Löcht teaches away from the claimed subject matter.

SEQ ID NO:11 corresponds to positions -76 to -46 of the PR2 promoter as shown in Figure 3 of van de Löcht (attached). Van de Löcht identifies that positions -168 to -52 are necessary for elicitor-mediated gene expression (page 2947, left column, last paragraph). In addition, the van de Löcht observed that the region from -168 to -108 was critical for GUS activity (page 2947, left column, second paragraph). Furthermore, van de Löcht teaches that a regulatory sequence between positions -168 and -52 appears to be both necessary and sufficient to mediate elicitor response (page 2949, left column, third paragraph). Finally, van de Löcht prompts the skilled person to search for elements modulating the level of basal expression within positions -168 and -108 (page 2949, left column, third paragraph and last paragraph). This clearly teaches away from the claimed sequence, SEQ ID NO: 11, which corresponds to positions -76 to -46.

A person of ordinary skill in the art, relying on the teachings of van de Löcht would chose a cis-element for duplication that ranges from -168 to -52, and not SEQ ID NO: 11, which ranges from -76 to -46. The bases from -52 to -46 are nowhere considered to have any influence in van de Löcht. Consequently, it is not taught by van de Löcht that SEQ ID NO: 11 (bases -76 to -52) is a cis-element capable of mediating local gene expression upon pathogen infection. The skilled person would not have identified SEQ ID NO: 11 as a cis-element and, thus, duplication of this element was not obvious from van de Löcht, whether alone or in combination with any other cited reference. Likewise, the skilled person would not have contemplated using a sequence comprising SEQ ID NO: 11 for duplication in view of van de Löcht, because a portion

identified as being necessary and sufficient for elicitor responsiveness does not comprise the entirety of SEQ ID NO: 11.

According to the teachings of van de Löcht, PR2 will not function without the region from -76 to -168. "These data show that the 116 bp between positions -168 and -52 of the PR2 promoter are necessary for elicitor-mediated expression of the gene." *Id.* Based on the teaching of van de Löcht, a person of ordinary skill would not think to use the region from -76 to -47, as this region excludes part of the sequence van de Löcht teaches to be necessary for elicitor-mediated expression (-168 to -76), and includes a region van de Löcht teaches not to be necessary for elicitor-mediated expression (-52 to -47).

As evidence that a skilled artisan would understand the article of van de Löcht to teach away from the claimed invention, Applicants refer to the declaration of Dr. Imre Somssich submitted March 12, 2007.

The credentials and expertise of Dr. Somssich are described in paragraphs 1 through 3 of the Declaration. Dr. Somssich addresses the teachings of van de Löcht in paragraphs 6. Dr. Somssich points out that van de Löcht observed no elicitor-specific expression using promoters pPR2-11 and pPR2-12, both of which encompass SEQ ID NO: 11. In paragraph 6, Dr. Somssich attests that the claimed invention performs surprisingly well when employed in synthetic promoters, and cites for further evidence the article of Rushton et al (*The Plant Cell* 14, 749 – 762, 2002).

Applicants respectfully request the Examiner reconsider the rejection. Van de Löcht reported no elicitor-specific expression in some cases in which SEQ ID NO: 11 was present, and

furthermore reported that one portion of SEQ ID NO: 11 serves no function in elicitor-specific expression. Therefore, based on the teaching of Van de Löcht, it would not be obvious to one skilled in the art to create a chimeric promoter comprising two elements of SEQ ID NO: 11. As such, Applicants respectfully request the Examiner withdraw the rejection and allow the claim.

B. SECONDARY REFERENCES TEACH AWAY FROM THE CLAIM

As evidence that the cited references other than van de Löcht would not render the claimed invention obvious to one of ordinary skill in the art, Applicants submit the Declaration of Dr. Somssich.

In paragraph 7 of the Declaration, Dr. Somssich addresses the article by Pears. Dr. Somssich explains that Pears teaches away from the insertion of heterologous promoter sequences inserted into promoters, as Pears observed the insertion of a heterologous promoter into a promoter sequence did not mediate expression of the actin15 gene. The inserted sequence ("oligo L") was only effective when inserted into a homologous promoter. Moreover, Pears observed that an inserted sequence was only capable of mediating expression in a homologous gene when inserted into a position normally occupied by a very similar element. As a result, Pears teaches that chimeric promoters of the claimed invention are incapable of effectively mediating gene expression. Pears teaches away from the claimed invention.

Dr. Somssich addresses the article by Searle *et al.* in paragraph 8. Dr. Somssich points out that, although Searle observed that multimeric elements of a metal-responsive promoter conferred zinc-dependent expression that was absent in the monomer, other investigators have

observed the opposite with other promoter elements. As a result, the findings of Searle would not render obvious the use of mulimeric SEQ ID NO:11 to obtain conditional expression.

Dr. Somssich addresses the article by Comai *et al.* in paragraph 9. Dr. Somssich points out that, although Comai observed a twofold enhancement of expression levels when 35S promoter was joined with the *mas* promoter, Comai obtained conflicting results as to whether this approach works generally for all promoters. In fact, Comai observed negative results when some regions of the 35S promoter were used. Dr. Somssich points out that Odell et al. found that duplication of the same 35S promoter produced no enhancement of expression. As a result, there is no clear teaching in Comai that multimeric promoters can reliably enhance expression.

Applicants respectfully request that the Examiner reconsider the rejection. The cited references teach away from the claimed invention, or at least provide no indication that the claimed invention would function for its intended use. As such, Applicants respectfully request that the Examiner withdraw the rejection and allow the claims.

VI. CONCLUDING REMARKS

For at least the reasons set forth above, all currently pending claims are believed to be patentably distinct from the prior art. Applicants respectfully requests the Examiner reconsider and withdraw all rejections, and allow all claims.

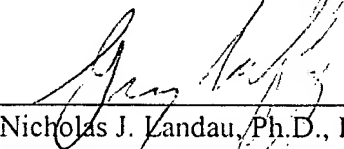
Although no fees are believed to be due, authorization is given to charge any fees due with the filing of this paper and credit any overpayments to Deposit Account No. 50-0951.

This submission is believed to be fully responsive to the pending Office Action, and the application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicants invite the Examiner to call the undersigned Greg Lefkowitz (direct line 561-671-3624) if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

AKERMAN SENTERFITT

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Nicholas J. Landau, Ph.D., Reg. No. 57,120
Gregory M. Lefkowitz, Reg. No. 56, 216
AKERMAN SENTERFITT
P.O. Box 3188
West Palm Beach, FL 33402-3188
Tel: 561-653-5000

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pr2 promoter region:

The sequence of SEQ ID NO:11 (positions -76 to -46) is given in bold.

The element identified by v.d.Löcht starts at -168 and ends at -52, as indicated in Figure 3 of v.d.Löcht.